

# Notice of Allowability

Application No.

09/992,832

Examiner

Blessing M. Fubara

Applicant(s)

SANDLER, ADRIAN

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to communication filed 09/29/04.
2. ☒ The allowed claim(s) is/are 1-44.
3. ☒ The drawings filed on 16 January 2001 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) ☐ All b) ☐ Some\* c) ☐ None of the:
    1. ☐ Certified copies of the priority documents have been received.
    2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\* Certified copies not received: \_\_\_\_\_.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.  
**THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
  - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
    - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date \_\_\_\_\_.
  - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date \_\_\_\_\_.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

## Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date \_\_\_\_\_
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date \_\_\_\_\_
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other \_\_\_\_\_

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

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### **DETAILED ACTION**

Examiner acknowledges receipt of amendment and remarks filed 07/29/04. Claims 1-44 are pending.

#### Status if Withdrawn Claims:

Examiner agrees with applicant that it was agreed during the interview of 21 July 2004 that when allowable subject matter is identified, the search will be extended to the non-elected claims and the restriction requirement would be withdrawn. In accordance with the above and recognition of allowable subject matter, non-elected claims 19-29 and 42-44 are now rejoined with the elected claims 1-18 and 30-41 (Official Gazette notice dated March 26, 1996 (1184 O.G. 86)). Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made in the Office action mailed on 06/18/2003 is hereby withdrawn.

#### ***Allowable Subject Matter***

1. The following is an examiner's statement of reasons for allowance: White (US 5,760,095) discloses a method of assisting persons in discontinuing the intake of caffeine; the method comprises simultaneously administering varying proportions of dosage units of caffeine and analgesics and where the method comprises administering a first dosage unit that has an equivalent daily caffeine intake that is followed by reduced level of caffeine, then gradually reducing the proportion of caffeine until the subject no longer ingests caffeine. The dose of analgesic administered with the caffeine is increased or decreased as the caffeine dose is decreased. A preferred embodiment contemplates a solid dosage regimen in which caffeine and analgesic are combined in one unit dose. In the alternative, a placebo is administered with the

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caffeine instead of the analgesic. See abstract, Figures 1-6, column 1, line 56 to column 4 line 67, example 1-7 and claims 1-13. White differs from the instant claims in that White discloses a method of reducing a subjects' dependence on caffeine and not on methylphenidate or dextroamphetamine; and in some cases, placebo is administered at the final stages of the regimen and the placebo is not administered with the caffeine. Dariani et al. (US 6,255,325) investigates the effect of the D-isomer of methylphenidate over the racemate dl-isomer of the methylphenidate in the management of attention deficit disorder (ADD). Placebo is administered at the start of the studies to all subjects at visit 1 to serve as a baseline and again at one of the visits. See abstract, column 3, lines 25, 43-67; column 4, lines 7-16; example 1 and claim 1. Dariani differs from the instant claims because the method of Dariani was not to reduce the amount of methylphenidate administered to a subject in need thereof as is the instant method, rather Dariani discloses a method to determine which isomer of methylphenidate is effective in the management of ADD by administering the d-isomer, the racemate dl-isomer and a placebo. Also, Dariani does not administer the placebo at the same time as the methylphenidate, the d- or the dl-methylphenidate. The pending claims are thus allowable.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BF

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